Institutional Review Board Initial Protocol Review Form

Principal Investigator: _____

Signature: _____

Address: _____

_____

Co-Investigators: _____

Protocol Title: _____

Source of Support: _____

Proposed Start Date: _____

Estimated End Date: _____

Approved By: _____

If your project has been/will be submitted to another Institutional Review Board, list name here:

_____

Status: ☐ submitted ☐ accepted.

Date: _____

Provide a brief description of study in lay language. Limit to space provided.
Purpose and background:

Subjects, number, gender, source, and selection method: (circle if any subjects are classified as minors, prisoners, pregnant women, abortuses, mentally disabled, students>18, non-English speaking)

Inclusion/Exclusion criteria of subjects:

Methods and Measures:

Specify clearly the expected outcomes:

Anticipated benefits to subjects:

Describe risks and side effects (physical, psychological, or social) and precautions to minimize risk:

Describe consent process, assurance of confidentiality, and any cost/remuneration to subjects:

Principal Investigator Statement of Assurance:
The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project prepared in accordance with the MCN Institutional Review Board policies for the protection of human subjects participating in research. I certify that I have read

the summary of the Belmont Report. I understand IRB policies concerning research involving human subjects and agree to:

a. obtain voluntary and knowing informed consent of subjects capable of providing consent who are requested to participate in this project;
b. report to the IRB any unanticipated effects on subjects which become apparent during the course or as a result of experimentation and the actions taken as a result;
c. cooperate with the IRB with the continuing review of this project;
d. obtain prior approval from the IRB before amending or altering the scope of the project of implementing changes in approved consent form;
e. maintain documentation of consent form and progress reports as required by institutional and federal policies;
f. accept the responsibility for the conduct of this research and the supervision of human subjects as required by law;
g. not profit economically and that I do not own a/any company or other commercial enterprise, wholly or in part, that will profit economically, directly or indirectly, from the execution of this study and/or the publication of its results.

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of Co-Principal Investigator Date

IRB Protocol Checklist: (attach a copy of each item)

- **Description of study in lay language**
- **Copy of consent form in subjects' primary language**
- **Protocols with minors as participants, if applicable**
- **Principal Investigator Statement of Assurance**

Submit all completed forms to tlyons@migrantclinician.org with a subject name to include "IRB" :

Addendum:

- **Guidelines for Informed Consent with Checklist**
- **Protocols with Minors as Participants**
- **Form for Drugs, Devices, or other active agents**
- **Summary of the Belmont Report / Helsinki Declaration**